REMARKS

I. Preliminary Comments

The present invention is directed to the discovery that allograft rejection in a transplant recipient can be prevented by administering to the recipient an antigenic preparation presenting antigens characteristic of the allograft. The appropriate dosages are typically low and can be determined empirically by those of ordinary skill in the art. The specification teaches one such method wherein the amount administered is a five-fold dilution below the highest dilution which elicits a positive wheal/flare response to a skin test in which the antigenic preparation is intradermally administered to the skin of the transplant recipient.

Claim 1 has been amended to recite that the method of preventing allograft rejection in a transplant recipient is carried out in the absence of generalized immunosuppressive therapy. This amendment is supported by the disclosure at page 3, lines 29 and 30 and does not introduce new matter into the application. Accordingly, claim 9 reciting combination therapy with additional immunosuppressive therapy has been cancelled.

II. Outstanding Rejections

Claims 1, 2, 5-9 and 11 stand rejected under 35 U.S.C. §102(b) as being anticipated by Posselt et al. *Science* 249: 1293-1295 (1990).

Claims 3, 4, 10 and 12 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Posselt et al.

Claims 1-12 stand rejected under 35 U.S.C. §112 (second paragraph) as being indefinite.

Claims 1-12 stand rejected under 35 U.S.C. §112 (first paragraph) as lacking enablement.

III. Patentability Arguments

A. The Rejection Under 35 U.S.C. §102(b) Over Posselt Should be Withdrawn.

The anticipation rejection over Posselt should be withdrawn in light of the amendment of independent claim 1, from which all remaining claims depend, to specify that method of administering an effective amount of an antigenic preparation presenting antigens characteristic of the allograft to the recipient is carried out in the absence of generalized immunosuppressive therapy. This is contrary to the practice and teaching of Posselt which discloses the use of generalized immunosuppressive therapy by the administration of rabbit antiserum to rat lymphocytes (ALS) and/or the transplantation of the allograft to the thymus which it identified as "an immunologically privileged site." (See pg. 1293, col. 2) Specifically, Posselt teaches that: "[i]dentification of a proper control was difficult, because (except for implantation in the thymus) no method allows permanent survival of fresh islet allografts in nonimmunocomprimised rats." (See pg. 1294, col. 2, last paragraph, emphasis supplied)

Thus, Posselt fails to disclose prevention of rejection in a transplant recipient by administering an antigenic preparation presenting antigens characteristic of the allograft in the absence of generalized immunosuppressive therapy and the rejection of claims 1-2, 5-8 and 11 under 35 U.S.C. §102(b) should be withdrawn.

B. The Rejection Under 35 U.S.C. §103(a) Over Posselt Should be Withdrawn.

The rejection of claims 3, 4, 10 and 12 as being obvious over Posselt should also be withdrawn given the failure of Posselt to either disclose or suggest the invention of claim 1. Not only did Posselt fail to disclose the subject matter of amended claim 1 but it teaches away from Applicant's invention by its suggestion that the allograft must be either administered to an "an immunologically privileged site" or that the transplant recipient be

subjected to immunosuppressive therapy. Accordingly, the rejection of claims 3, 4, 10 and 12 under 35 U.S.C. 103(a) should be withdrawn.

C. The Rejection Under 35 U.S.C. §112 (second paragraph) Should be Withdrawn.

The rejection of claims 1-8 and 10-12 under U.S.C. 112 (second paragraph) for indefiniteness should be withdrawn because "antigens characteristic of the allograft" is clear to those of ordinary skill in the art as meaning antigens corresponding to those presented by the allograft. Thus, the specification teaches at page 3, lines 18-24 that preferred antigenic preparations comprise donor tissue which has been mechanically homogenized. The specification further teaches that antigens from sources other than donor tissue may be used which are combined to "replicate the antigenicity of the donor tissue." (page 3, line 24). Accordingly, the claims are not indefinite to those of ordinary skill in the art when read in light of the teachings of the specification and the rejection under U.S.C. §112 (second paragraph) should be withdrawn.

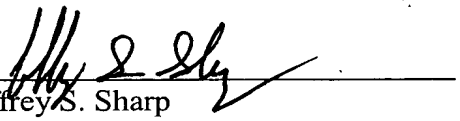
D. The Rejection Under 35 U.S.C. §112 (first paragraph) Should be Withdrawn.

The rejection of claims 1-8 and 10-12 under 35 U.S.C. §112 (second paragraph) for lack of enablement should be withdrawn as it is well within the ability of those of ordinary skill to practice the present invention when provided with the teachings of the specification. The test for enablement is not that of perfection or of certainty but whether those of skill are enabled to practice the invention and whether a benefit (however imperfect) is provided by practice of the invention. In light of the severity of consequences that otherwise ordinarily occur with allograft rejections it is submitted that such a benefit is provided by the present invention and that accordingly, the rejection under 35 U.S.C. §112 (second paragraph) should be withdrawn.

The Commissioner is authorized to charge any fee deficiency required by the paper to Deposit Account No. 13-2855.

Respectfully submitted,

MARSHALL, GERSTEIN & BORUN
6300 Sears Tower
233 South Wacker Drive
Chicago, Illinois 60606-6357
(312) 474-6300

By: 
Jeffrey S. Sharp
Registration No.: 31,879
Attorney for Applicant

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